week from every supplier that we buy from.

MS. SMITH-DEWAAL: We have heard earlier today that some people test as frequently in grinding operations once every 15 minutes. Do you have some people who you supply to that require that level of testing?

DR. HOLLINGSWORTH: That I supply to? Do you mean do I have customers who require me to test every 15 minutes? I think I will have to answer that with that is a matter of the individual company specifications, and if that individual company does not choose to give that information out, I would prefer not to, as to how often they test.

MR. BILLY: Other questions? Yes, Heather.

MS. KLINKHAMER: Heather Klinkhamer with Safe Tables Our Priority. I have actually several questions. I wanted to start with Dean Danialson. When you made your presentation, you said that you were speaking on behalf of an industry coalition. Could you tell us who are the members making up this coalition?

MR. DANIALSON: Excuse me. Dean Danialson. I'll just kind of wheel through a list of the ones that I can recall that have been involved, and I am going to miss a few. But, Kim -- maybe I'll defer that to the AMI because they have been somewhat spearheading the effort, and she can probably reel off the names and associations more completely than me.

MS. RICE: The majority of the work was done by a task --

MR. BILLY: Kim, state your name.

MS. RICE: Oh, sorry. Kim Rice, AMI. The majority of the work was done by a task force of AMI membership that was not only slaughterers but also grinders, large and small. We brought in or asked for participation from also non-members who had interests in the slaughter and the grinding, and also some of the customers of these members, as well as the retail outlets and other trade associations. So, I mean, it is pretty broad based.

MS. KLINKHAMER: Would you be willing to give us a list for the record?

MS. RICE: I'll talk to them about it.

MR. BILLY: Other questions?

MS. DONLEY: Nancy Donley, Safe Tables Our Priority. One question that I have, I guess, of the coalition here is how do you marry, if you will, the idea of testing carcasses as opposed to point four, which I'm sure you all remember, of the eight points that the American Meat Science Association, Mr. Keeton, presented, which states that food borne pathogens will not be detected consistently when they are non-randomly distributed and/or occur at a low incidence. And we know that for a fact with 0157:H7 and its incidence on carcasses.

It seems to me that if we are really interested in finding it, if it is there, we are more likely to find it, if it is there, when it is in a situation where the pathogen would be more evenly distributed. And that, I would suggest, would be in something more as in trimmings.

MR. BEILA: Tim Beila, American Food Service Corporation. I want to address that question as best I can because I believe that you may have a little bit of a misconception there. Depending upon how much upgrading is taking place when a carcass is being broken and how much meat is being taken off that goes out as primals and sub-primals will vary from plant to plant and from the type of animal that is actually being slaughtered, fat cattle and cows.

If you look at combo then sampling and testing, less than 7 percent of the surface material on a carcass actually ends up in a combo bin, and it doesn't seem like the appropriate place to go looking for it. Its numbers have been extrapolated between one and 7 million and one in 20 million opportunity to detect, depending upon the type of methodology for collecting the sample in combo bins. And that was based on trimming, coring, purge sampling. And there has been a lot of research done that says that purge is not a good method for collecting a sample.

So going to the carcass and exposing or sampling a

very large portion of the surface relative to the carcass and testing for 0157 may hold promise for a statistically valid method of detecting and reducing the risks associated with the organism versus combo bin sampling and testing. What we are asking for is the opportunity to be able to continue with the raw material sampling and testing programs that exist today in combo bins until the research and analysis of that research can be carried out on carcass sampling and testing.

But again, the surface of the carcass is where the contamination is occurring. Going to the surface of the carcass may in fact give you a better statistical representation or ability to detect the organism.

MS. DONLEY: Nancy Donley, STOP. So are you positioning this then as a kind of a let's hold back thing, wait and see, because what we would like to do is conduct this study, and if this study shows that carcass testing is the way to go, and that we can get a good idea of just what kind of loads carcasses are carrying, what frequency they occur, that this then after -- that this study would be conducted prior to any change in directive 10010.1. What is the time frame or time -- the progression, I guess?

MR. ALLEN: I'd like to address that, Nancy. Dell Allen. I think it is imperative that the directive be changed, and maybe it happens after the carcass testing, I

don't know, or after this pilot test. I don't like -- I get nervous when people talk about a research project. We work in a commercial facility, and commercial facilities are not designed for research projects.

I think we can get some numbers of what is going on. I am not going to -- I don't think I want to characterize it as a research project. Research projects to me are much more intensive in their nature, and should probably more properly be carried out in a research facility than in our commercial labs.

But getting back to the directive, to me, if we have got -- I talked about the carrot and the stick. The industry, I think, needs the carrot to be able to move forward in this whole thing before they are going to be real willing and -- it is very critical that we have that carrot to take that next step.

MS. DONLEY: What is the carrot for the public?

MR. ALLEN: I think the carrot for the public is an immediate increase in the number of tests that are going to be conducted for 0157:H7.

MS. DONLEY: But I guess what I am not comfortable with is knowing that conducting the -- I think your number was 94,000 tests will be conducted -- that we don't have any sort of data that supports that that will indeed be effective in culling out 0157 at a significant rate from

getting into the system. We have no data showing the prevalence of carcass contamination with 0157 to begin with. I think that is the problem. And so if we knew that -- I don't know if 1 in 300 is a good number, if it is a bad number, if it is an indifferent number. I don't know if we need to be testing 1 in 50, 1 in 500. We don't know.

MR. ALLEN: Nor do we. And I think that is why we need to take this step. I mean, that is really where the industry is. I think one of the things that needs to be put in context that we failed to do in our presentation, because most people don't understand the complexity of testing for this organism -- and I'm talking about just the time, the manpower required to do it.

First of all, at least in our slaughter facilities, at least to this point -- and I'm probably getting ready to change it. But we have had a rule that we will not do pathogen testing in any plant that we work -- you know, any in-plant laboratory. I think the reason is obvious, you know. You don't want to fool around with pathogens in a production facility where you might even have the remote chance of getting them out of control.

So when we test for a product -- for this organism, we send that test out. It goes out by air express, Federal Express, one of the courier systems, to an outside laboratory, a third party laboratory. But when you

operate in Friona, Texas, folks, and other places like that, air service is not the greatest, you know. And so when we are operating two shifts, the samples that we collect after about anywhere from noon to 3 o'clock in the afternoon sit until the next day before they get air freighted. And then if you really want to get it complex, do it on a Friday night, when they don't ship on Saturday. Then you have a got a Friday evening kill that you tie up then until Monday before you can actually get the sample out, okay?

One day of getting the sample to the lab, at best, under the best conditions. After they have gotten the sample, it takes them one day basically to prep it and get back your first results, which are either a negative, which is what you want, or a presumptive positive. If it is a presumptive positive, then typically it is at least two additional days before you get the final results back. And so you are sitting there -- and again, if you think of the Friday evening kill where we didn't get the sample out until the following Monday. If it is a worst case scenario, we get results back; it is almost the next Friday. We have held that product for one week.

We literally don't have the capacity to hold product and test it. If we had moved to an in-plant lab -- I have already addressed this with my laboratory people, for a plant laboratory. And it won't be in-plant, it will be

off-site, but near the plant, where we are doing the testing on our own. First of all, it is going to take qualified people. You don't do this with Joe Blow off the street, pardoning my expression. But it has to be somebody that is fairly, highly trained.

Secondly then, under the best scenario, to go through the pre-enrichment phase of that test, my lab people tell me it takes one person to do 12 of those pre-enrichments, 12 tests, 8 hours to get it done, the pre-enrichment part. So if you are talking about a lot of tests, there is just no way we have the physical capability of doing it at this time.

Now I would say that there are a lot of dollars being addressed -- and I defer this to Randy and Jim Marsden over here and some of the people that know. There are a lot of people working intently on getting a very rapid testing method for this organism. I'm convinced it will happen. If and when it happens, I think we will be very willing to step to the plate and do more testing. But the limitations are what we are talking about right now that keep us from that. And it just will physically cannot handle much more.

MR. BILLY: Do you want to continue, Nancy? Heather?

MS. KLINKHAMER: Heather Klinkhamer with STOP. I wanted to follow up. I had a question for Warren at Con

Agra. In your slides, you mentioned some multiple plants have been tested. Is that the six out of the eight Con Agra plants?

MR. MIRTSCHING: We tested all eight facilities.

MS. KLINKHAMER: Okay. And the testing went from September to December of 1998?

MR. MIRTSCHING: That is correct.

MS. KLINKHAMER: Okay. And will there be a peer reviewed study published based on this information?

MR. MIRTSCHING: That will come through the CSU and NCBA.

MS. KLINKHAMER: Do you know if they have submitted their data to a publication?

MR. MIRTSCHING: No, I do not.

MR. BILLY: Caroline.

MS. SMITH-DEWAAL: Caroline Smith-Dewaal, Center for Science in the Public Interest. Tom Beila just said that the way we are going to get greater statistical certainty here is by carcass sampling using a large proportion of the carcass. How big is the sampling -- how much of the carcass are you proposing to sample in what you proposed today?

DR. HOLLINGSWORTH: What we are proposing, at least until we can do additional tests that might show us additional ways that we can find it, is essentially the same

way that we currently are testing for generic E. coli on the carcass, which includes at the knife point. And Dell is going to put it up there. On his presentation, his last slide showed those points, if he can find the switch. There we go.

The places where we have traditionally been most successful in finding it, which is along the midline, where the carcass is opened -- where the hide is opened, excuse me, and on the back of the round of the animal, which is between the two hind legs, and then down on the bottom, where the throat is, if you will, those are the places that we would say that initially should be tested. We have plans as well, if this pilot program is approved, to do additional testing to determine if there are better places to find it.

MS. SMITH-DEWAAL: Okay. So what you are proposing initially is that you would sample it the same sampling frequency as we now have the generic E. coli sampling occurring and the same sites?

DR. HOLLINGSWORTH: The same sites. However, right now, the one site -- the generic E. coli is done on one side of the carcass. And we're saying that you will take the other side to do the E. coli 0157:H7 test. If a plant chooses to go with a wholly different carcass, they may also do that. But what we are proposing is since you are already isolating the generic E. coli carcass, that the

other half that is not being tested today would be tested for E. coli 0157:H7.

MS. SMITH-DEWAAL: And exactly what questions will the pilot test resolve for us? I mean, because I can see -- I have a lot of questions about -- as Nancy said, the 1 in 300, whether that is enough, whether we are testing enough of the carcass, is that what Tom meant by a huge proportion of the carcass. I could see it being bigger than what you are proposing. How many of these questions that are being raised at this meeting is the pilot test going to resolve?

DR. HOLLINGSWORTH: It is our plan to try to address all of those questions. Some of those questions we have for ourselves, and some of them we don't. The first question that we want to ask and get an answer to is what is the prevalence of the organism coming into the back door. So we are going to do some live animal tests so that we know across a number of different slaughter plants, not just done at one slaughter plant, what is the prevalence coming in. Then we are going to test at the various hurdles, much like what the study that Warren presented to you was done, what is the reduction after those various points in the process.

Have we been successful when we removed the hide at not carrying the organism from the hide onto the carcass? Have we been successful after a pre-evisceration wash in reducing it further, et cetera, et cetera. That is one

test, one pilot test that we would like to do to verify that, number one, if it is there we can find it, or that the intervention systems are eliminating it.

MS. SMITH-DEWAAL: And you are saying you would test for 0157:H7?

DR. HOLLINGSWORTH: Yes. That is correct. The second test would be done in a research environment where we would look at other potential methods for swabbing to verify that we can get the organism off the carcass by -- that our swabbing methods are effective. If the organism is there, are our swabbing methods effective?

MS. SMITH-DEWAAL: And so out of the pilot test, you may come back to the department with additional recommendations for how sampling should occur, the frequency of sampling, the sites for sampling, what tests should be utilized. Is that accurate, that you would come back to the department with information on how to best do the -- how to best they require you to do the test?

MR. ALLEN: I think the key point here, Caroline, that hasn't been made maybe -- and it is a good point you are making. Our intent, if we go this pilot test period, all of that data will go to the department. They will have all of that data.

DR. HOLLINGSWORTH: So to answer your question is yes, it is our intent that if there is something that we

find out in this that is different than what we think we know today, we would come back with that information.

MS. SMITH-DEWAAL: But Dell just made a very important point.

DR. HOLLINGSWORTH: Yes.

MS. SMITH-DEWAAL: So all the data, good or bad --

DR. HOLLINGSWORTH: Yes.

MS. SMITH-DEWAAL: -- that suggests a change, doesn't suggest a change. Everything will go back to the department with respect to the pilot.

DR. HOLLINGSWORTH: Yes, absolutely. And the key point here is that this group is interested in reducing and/or eliminating this organism to provide a safer food supply to the public.

MS. SMITH-DEWAAL: And then my final question. In terms of what you are proposing the department do in terms of modifying their regulation, do you see this as a preliminary step prior to the data coming back from the pilot test?

DR. HOLLINGSWORTH: We believe there are a couple of ways that they can approach this. They can hold in abeyance the clarification as they publicized on January 19 for an additional 180 days for us to do the test. They can make the changes that we recommend with the clarification that they may change them again after this 180 day test

period. Either/or is fine with us.

MS. SMITH-DEWAAL: And the two biggest changes are, just to really nail this down, are to -- that companies that do intervention, that companies that will be exempt from -- what? -- retail testing, from testing in the plants -- I mean, what is the -- just clarify for everybody the current practice and what will be -- who is going to be exempt.

DR. HOLLINGSWORTH: Okay. First off, we are not suggesting that anybody is exempt. Secondly, what we are asking for or proposing is that these intervention steps and carcass swabbing methodology for reduced sampling is carried through to all levels in the food chain, that it allows you to be eligible for reduced testing if you follow these procedures. If there is a reason to believe that there has been an epidemiological problem, someone has contacted EC-H7 and there is a problem, all bets are off. We are not saying that that is going to change.

In the event that someone gets sick and any of our products are implicated, then we understand that we still have to protect the public, and that we are willing to accept that. What we are asking for is that as long as we are trying to make this happen, we are trying to reduce the organism, we are trying to eliminate the organism, to allow us the opportunity to get this information without putting

us in a penalty box. And the reason that the directive hasn't been utilized any more strongly than it has to date is the six month penalty, essentially, that you have to have six months of negative data.

And we are saying that if we find positive, that stuff is removed from the chain, from the supply chain. Any positive is removed from the supply chain. And therefore, the requirement for six months of negative data should go away. That is in my mind the biggest change we are asking for.

MS. SMITH-DEWAAL: So you are saying that once a plant implements carcass sampling together with these intervention techniques, at that point, they should immediately be exempt from random E. coli 0157:H7 testing by the U.S. government.

DR. HOLLINGSWORTH: We are saying that they should be eligible for reduced testing. We are not saying that they are exempt. The agency has never given anybody an exemption from testing for E. coli 0157:H7.

MS. SMITH-DEWAAL: Maybe my questions actually goes to Mr. Billy. There is a lot of confusion about what the exemption is, where it is applied. I mean, my understanding is that once a company implements this directive, that they won't be tested, either in the plant, or I believe at retail for 0157:H7,as part of your 5,000

sample random sampling surveillance program. But if there is clarification there, please.

MS. STOLFA: Hi. This is Pat Stolfa, FSIS. The directive, as it is now in place, applies to ground product testing, some of which occurs in retail locations, and some of which occurs in official establishment locations. It does not apply to carcass testing at the present time. And I think that -- and my understanding is the same, that it does not qualify one for an absolute exemption. It does qualify -- if one of the three criteria are met, what the establishment has is the possibility of reduced testing because the inspector, via the directive, is given instructions that he may choose not to take a sample when he receives the form that generally instructs him to take a sample.

And what was your other question?

MS. SMITH-DEWAAL: Well, I'm wondering, the application of that ground beef testing requirement then to a plant that does, as they proposed -- that has multiple interventions and does carcass swabbing, what would be the impact on whether they would get tested?

MS. STOLFA: Well, it depends on whether or not the grinder, which is subjected, you know, potentially subjected to the testing, has documented a system that meets one of the three criteria.

MR. BILLY: Remember that the -- as I recall the presentation, it talked about records that would associate the raw material with one or more of the plants that are part of this kind of approach and, you know, that if they used other material from plants that weren't part of this, then that would be a different situation. So I think we need to see the whole proposal. But it sounds like it is designed to provide a continuity from the slaughter plants on through to the marketplace, is what I heard. I don't know if you want to amplify on that some more to help people understand.

MS. SMITH-DEWAAL: I just want to be clear. So this directive just has the promise that they may get reduced testing, if they do more sampling. And all you want is a promise that maybe they will reduce their testing. You are not going to be exempt from testing. Is that accurate?

DR. HOLLINGSWORTH: Well, I think certainly if we were going to be guaranteed we weren't going to be asked for testing, we would say yes.

(Laughter)

DR. HOLLINGSWORTH: But that's all we are asking for. All we are asking for is essentially the status quo, but we would like to pass it on through the market chain.

MR. ALLEN: Just a clarification, Caroline. Dell Allen. We now are eligible for reduced testing. Our

inspectors still get requests to pull samples. When they get those, they come to us, or we go to them, usually. We don't wait on them to come to us. And basically, we have to share with them our records on the testing that we do, plus -- they still have, even after that, they still have the option -- in fact, we have had them take it anyway, whether they shared the records or not.

So it is not -- I sincerely wish it were an exemption. But I have never gotten that word out of the department.

MR. WOOD: Richard Wood, Food Animal Concerns Trust. By the way, the greater hope that the comments that you made this morning on paper will be made available to us -- I stopped taking notes about five minutes in, and it sounds like an important proposal for us all to look at and think about.

In the proposal, with an increased carcass testing, I was hearing, I think, that the supplier end of things was minimized. And at the other hand, I thought I was hearing that if the prevalence of E. coli or E. coli 0157:H7 or other pathogens were found, that may raise some red flags. In your proposal, is there any part of that proposal that deals with steps that you might take with your suppliers, particularly producers, to the slaughterhouses, and what might those steps be?

MR. ALLEN: Excuse me. All right. We have definitely discussed what we would consider doing. Yes, our decision is it is not totally appropriate for us to make that decision. Then again, I think part of it again depends on what is found out in this pilot test, you know, as to how that works out. We definitely have some of our own ideas on what should happen.

Basically, our concept is that we ought to address the E. coli 0157:H7 as best as we can on a process control model, which is where HACCP is, more so than just a flat, totally negative all the time type of approach. Because again, the negative all the time, believe it or not, is a deterrent to anybody wanting to even get in the box in the first place and start looking for it. It is a visible deterrent. I know that may be difficult for some people to comprehend, but it is there.

MR. BILLY: That was Dell Allen from Excel.

MR. DANIALSON: Along those lines -- Dean Danialson, IBP. If the positive event occurs in a carcass testing program, there are several events that any responsible organization would take in the spirit and application of HACCP, and that involves going back and of course taking care of the product that is affected, and this would be the carcass. You would go back and review your process, investigate your process, measure/check the CCPs

that are in your process and the control points in your process.

You go through that activity all the way through. It becomes an investigative process. At the carcass level, we have then the opportunity to look further back into the supply chain in the surveillance mode to see and understand better location effects, seasonal effects, and those types of activities. It gives us the opportunity to get a much broader amount of information when and if any event occurs.

Now obviously the thermal processes and all of the multiple hurdles, no one in this room would say they are 100 percent. But obviously, the science, the support, and the development that has gone in the last few years puts those systems in a much -- gives us a much greater confidence that we're addressing and enhancing food safety. And we wouldn't be going forward with this type of approach if we didn't think that there was significant effect that these systems are going to offer us in terms of reducing the incidence of the 0157:H7.

But when the positive occurs, in the HACCP concept, you go back and review all of your systems and processes. You couple it with other known information like the associated coli species information, is there a gross contamination situation, is it a spot random incident. This is information that we will learn as we go along, but we

want the opportunity to learn it as we go along.

MR. BILLY: Nancy.

MS. DONLEY: Nancy Donley, Safe Tables Our Priority. I would just like to say that the idea of a scientifically proven, statistically proven carcass sampling regime would be very welcome. I think it would lead to something that I think it could be very beneficial by weeding out at that earliest point carcasses that are contaminated with 0157. It makes great sense, as long as we know that -- I just don't think we're there yet, and that unless there has been a lot more that has gone on in this coalition meeting that I don't know about, the design of the program itself.

But we support the idea of carcass testing. Perhaps it has to be included as a part of where you have multiple hurdle interventions. Maybe we need a multiple testing -- I know that is going to go over real well in this room -- a multiple testing regime as well -- I'm just going to throw that out -- until we know that, hey, we can effectively address it at the carcass level. If we can, I think that is great.

I think what would be very helpful to me is, Ann, you had a slide, and there were a couple of slides that you showed us. I just am a very slow writer. If you could put it back up on your overhead. And it was the one where you

said you wanted to alter the third option to -- and you had --

(Pause)

MS. DONLEY: And what did you mean by alter the six month requirement?

DR. HOLLINGSWORTH: Alter the six month requirement for eligibility. Is that your question?

MS. DONLEY: Mm-hmm. Eliminate it.

DR. HOLLINGSWORTH: Our preferred word would be eliminate, simply because we believe that the six months negatives discourages you from trying to find the positives and remove them.

MR. BILLY: Carol.

MS. DONLEY: Thank you very much.

MS. TUCKER-FOREMAN: Carol Tucker-Foreman with the Safe Food Coalition. Would you, Ann and Dell and others if you want to address it, give us some specifics of why this discourages people from doing the testing. Talk to us about the specifics of that problem.

DR. HOLLINGSWORTH: A six months negative result means that if you are successful in finding it, even though you eliminate it from the system, you still have another six months before you can go into the reduced sampling program. It is very difficult, particularly if you are doing it at the carcass level, to guarantee -- if you are doing it at

any kind of reasonable level of testing. If you are testing one carcass a week, and you do that for six months, and you have all negatives, then chances are you would be able to meet it. But is that reasonable? I don't think so.

So our thought process is let's increase the sampling, which is what we are proposing to do, to a minimum of 1 in 300 carcasses slaughtered, and eliminate the six month requirement so that if we find it, all we are doing is removing it. We are removing it from the system. We are doing the investigation to find out why it was a positive, going back to the farm to determine what the origin was, and then we will continue forward.

And if we have another event during a specified time period, then we will put in a very rigorous corrective action plan.

MS. MUCKLOW: Can I interrupt just a minute, Dean, before you go? Is it permissible to ask you all why it is you incorporated the six months?

MR. DANIALSON: Mm-hmm.

MS. MUCKLOW: That being the answer, then I would ask the question.

MR. DANIALSON: Thank you. Dean Danialson. In terms of specifics, I want to expound on that just a little bit. As we understand 10010, it was basically, from my understanding, developed to offer industry an incentive to

pursue these enhancements. And 90 percent of it is right there. I mean, it truly can offer the incentive. However, you know, the six month aspect -- the whole formation of the infrastructure in the industry associated with developing into 10010 will result in downstream customers, grinders, perhaps maybe retailers, developing their associated programs and business relationships tied into this -- I'll use the word -- I won't use the word -- tied into meeting that 10010, any one of the three.

So in a business that has established these customer relationships, all of a sudden now gets a random positive event in a testing program. The entire business relationship of that facility is disrupted for six months. If you have established that infrastructure with the downstream customers that are relying on that compliance, all of a sudden you don't have anything -- anywhere to go with the cart for six months based on most likely a random, sporadic event that does not necessarily, at least to our understanding now, signify a process failure.

That is kind of the key to me on how that penalty of six months is a detriment to participating in the program.

MS. STOLFA: Pat Stolfa, FSIS. I think I can recollect how the six months feature was developed in the directive. Initially, it was designed principally to deal

with the fact that if an inspector were to offer a company the opportunity for reduced sampling, we didn't want inspection program personnel to do that on the basis of a company that said, well, I started my program yesterday, and I don't have any positives. So we said you need to have some history in order to demonstrate that the company has been doing this for awhile.

I think -- now again, my recollection is not perfect here. But relatively early in the process, as we were putting this in place, we were confronted with an international situation and an effort to try to make this work between companies that had close relationships either within their own corporate structure or -- I think it was mostly within their own corporate structure across the Canadian border.

And we wanted -- things got slightly more complicated then because our import program, when -- because remember now we're not testing carcasses. We're testing ground product. And I think the six months got more institutionalized in our effort to make it somewhat similar to other things that we did relative to a finding of non-compliance in imported products throughout the rest of our import testing program. And that is the best of my recollection.

And again, it was a ground product testing program

that we were designing, not a carcass testing program.

MR. BILLY: Are you finished, Carol?

MS. MUCKLOW: I am, thank you. That helps me a lot.

DR. WACHSMUTH: I wanted to pick up on something that Nancy said. It is something I was thinking as you were going through the presentations. It would be optimal scientifically if the testing on the carcass, if indeed you could follow this all the way to the end user or the retail, to during the pilot associate that with testing of ground beef, to see -- you know, to determine precisely how one relates to the other since we don't have those data. But instead, it sounds like, from what Dean said, that may not be a part of the plan. I wonder if anyone has comments on that.

Would it be possible to do this in association with testing ground product as well? Because I like the idea of the aggressive sampling, and going back as close to the farm as possible is absolutely what we would want to do. But it would give us the assurance that something isn't appearing downstream.

MS. MUCKLOW: I think the problem is that carcass gets co-mingled with a lot of other carcasses, and then I don't think that is a possibility, unless I am misunderstanding your question.

DR. WACHSMUTH: I don't know that it would have to be the exact same carcass. But if the flow were to be followed downstream and then testing of ground product associated in some way with this pilot, I think that would be optimal.

MS. MUCKLOW: I'm sure if there was a way to do it, the people who have thought the details of the program would try to work that out. But I think the commingling of product may deny that happening. But I'm sure they would be happy to think about that. And again, this is a very strong concept here today. As Dell said, it has taken us five years. We are probably five years too late with it today. But you guys weren't ready for it five years ago either. So, you know, we are all busy trying to put something together that would really be useful and beneficial, and beneficial to everybody.

DR. WACHSMUTH: Again, it is fine. And I am pleased. I think the closer you get to the source the better. The only thing that I was suggesting is that if there were a way to associate that, maybe even with current testing -- I know some of the people that you supply are probably testing. I would hate to see that discouraged until the pilot has a chance to evaluate the whole system.

MS. MUCKLOW: Tell you are pleased again. We like to --

(Laughter)

MR. BILLY: Ann.

DR. HOLLINGSWORTH: Ann Hollingsworth, Keystone Foods. One point we didn't make probably crystal clear is that during this 180 day pilot test, when the carcass testing will be verified, it is our intent as grinders to continue the testing programs we have of the trims. So I think, Kaye, the answer to your question is yes. But one thing you need to remember is that if we find a positive on a carcass, that carcass is removed from the system.

So it will not be a direct test combination. But, yes, it is our intent to until we are positive as grinders that the carcass testing will indeed pick up an out of control system, we will continue to test our trim. And it is our intent that we will do that for the 180 day test period, so there will be some correlation.

MS. TUCKER-FOREMAN: It's Carol Tucker-Foreman again. I want to make sure I haven't missed something here. Even though a positive carcass would be removed, we could attach ground beef sampling to your pilot. You could attach it to your pilot project if for no other reason to see that your proposal that carcasses that come through this system get some positive labeling as it has passed a higher standard. So it would seem that Kaye's suggestion that you test the ground beef to show that in fact the carcass

testing does have that impact would be a useful part of the pilot.

DR. HOLLINGSWORTH: Yes. It is our intent that that will be done. Those organizations that are doing testing now will not stop the testing that they are currently doing. That is part of the agreement across the coalition.

MS. TUCKER-FOREMAN: I wonder if maybe you need to do more of it so it is an integral part of the pilot so that you show that the theory actually does work out at the end of the line.

DR. HOLLINGSWORTH: Okay. I think we can arrange that.

MS. TUCKER-FOREMAN: I think that would probably be reassuring.

DR. HOLLINGSWORTH: I don't think that is a real difficult thing for us to add. The intensified testing that you are talking about in the product you are talking about, I don't think it is a difficult concept to incorporate into the test, the pilot test.

MS. TUCKER-FOREMAN: It is or is not?

DR. HOLLINGSWORTH: Is not a difficult --

MS. TUCKER-FOREMAN: That's what I thought.

DR. HOLLINGSWORTH: -- thing to incorporate.

MR. BILLY: Heather.

MS. KLINKHAMER: Heather Klinkhamer, Safe Tables Our Priority. I want to assume, but I want to make sure by asking, will you be preparing an outline or a detailed written document about what you are proposing? Will that be going to the docket at USDA by March 22?

DR. HOLLINGSWORTH: Absolutely.

MS. KLINKHAMER: Would you be willing to share your paper with the public sooner than that so that we can incorporate comments on that into our comments by the --

MR. DERFLER: We're working on it. But, yeah, I mean, this is going to be an open bid at some point.

MS. RICE: Kim Rice, AMI. I want to make sure I have got what you are asking for. Are you asking for our written comments, or are you asking for the protocol for the pilot? Because those are two different things.

MS. KLINKHAMER: What I am asking for is more details about this pilot before the comment period and the protocol.

MR. ALLEN: Dell Allen. I would address the protocol part. To get that by the 20th I think is going to be difficult. When our protocols are finally outlined, they will be available to the agency, which makes them available to the public. We're still wrestling with details, particularly like on the live animal and how we are going to sample, what we are going to sample. All of those types of

things have not been worked out yet.

MR. BILLY: If there was a sense coming out of this meeting that the addition of a week or two of comment time to facilitate providing the public in advance of the protocol and other related information so that they could incorporate their comments into -- include in their comments their reaction to the protocol, I think it sounds from the sense of the discussion here that that would be a good thing.

MS. TUCKER-FOREMAN: Yeah. It's Carol again. It seems to me that would avoid us having to write a set of comments on the proposal that might then be altered substantially by the details of your protocol. So maybe we could all get together and get some scheduling here that would make it possible for us not to have to be passing each other and stretch this process out forever. None of us wants to write comments on something that is going to be rendered irrelevant in the next step.

MS. MUCKLOW: The flexibility on extending the comment time is deeply appreciated.

(Laughter)

MR. BILLY: Do you have it in your pocket yet? Caroline.

MS. SMITH-DEWAAL: Thank you. Caroline Smith-Dewaal with the Center for Science in the Public Interest.

I have two questions regarding your proposal for altering the third option. One is that you move the phrase validation down -- or validated pathogen reduction steps now into being validated through carcass swabbing for 0157:H7. Don't you mean verified using carcass swabbing for 0157:H7? Shouldn't they already be validated and just the use of them is being verified? So that would be my first question. You don't have to answer it right now, but I'll be interested to see if that would change.

The second thing is you have removed the language and prevent the use of boneless beef or carcasses from outside sources. And I wanted to know whether that was intentional or not.

MR. DANIALSON: As I interpret it, it is not -- that will remain. It was unintentionally not included in there because it is just a status quo activity.

DR. HOLLINGSWORTH: It is not something we are changing.

MS. SMITH-DEWAAL: Okay. Do you have any comment on the validated versus verified issue?

MR. DANIALSON: Semantics.

MS. SMITH-DEWAAL: It is not really.

MR. DANIALSON: Well, the validation is a -- the pilot in essence is a validation. Ongoing testing becomes a verification.

MS. SMITH-DEWAAL: I would recommend you may -- having been a lawyer who sat through many meetings on this topic, that you want validated intervention, meaning those interventions proven to control 0157:H7, of which organic acids probably isn't one, and that the carcass swabbing is to verify that those interventions are in fact working. Perhaps I should make my proposal to the department, however.

DR. HOLLINGSWORTH: Caroline, this is Ann Hollingsworth from Keystone. I think it was just a -- as I go back and look at the two different languages, the intent was not to change the language that much, and I think we just got the V words mixed up, if you will.

MS. SMITH-DEWAAL: Perfect.

MR. BILLY: Can I -- and part of it ties into this a little bit, and I'll start with Dell maybe. Dell, you used the word carrot. And it would be useful, I think, for everyone if we sort of reviewed what it is that you view as the carrot. And I'll broaden that out to all of the coalition in terms of what constitutes the carrot here in terms of the proposal and your overall reaction to the policy change and clarification.

MR. ALLEN: Dell Allen. I'm glad you opened it up to everybody else because I may not cover the whole thing where I can see it. As I see it in the industry, the

alteration, if you will, of some of the mechanism on the 300 negative tests as it particularly relates to carcasses, I think that needs to be couched in some kind of process control model. That, as I have perceived it, and I think as most people have perceived it, notwithstanding what she said, we interpret that as being any test, whether it be -- of course, in fact I have talked to some of the people in the agency, and I get both reads on it, where one time it is ground beef, the other time it is any test, and so that is unclear. That is one of the big ones.

The other one is the definition of lot size and how we handle lots as it relates to trim positives so that that does not discourage the testing as far as trim is concerned. Those are the two of the biggest ones, I think, and then the other is the extension, if you will, of the reduced sampling incidents. If I'm on the program to the customers that I supply to and/or that purchase product from people who are on that type of a program, to me those are the big three carrots, or parts of that carrot, the top, middle, and bottom thirds of the carrot.

If I missed any, please --

MR. BILLY: That last item would include the retail -- passed through to retail on the ground beef or --

MR. ALLEN: Or sub-primals or in non-intacts or whatever that we deal with.

MR. BILLY: Rosemary.

MS. MUCKLOW: I would just like to add something for Caroline, and we can certainly find this if you don't have it, Caroline. I have heard you say several times this morning you are concerned about the use of acid rinses. There is some good research that has been done, and it is published research, that demonstrates that the use of lactic acid rinses following a thermal process magnifies and improves the results of both immeasurably. So we are still learning a lot about this microorganism. If you need that information, we'll dig out the research paper and send it to you. But I would hate anybody to go away thinking we are using the wrong stuff.

MR. BILLY: Carol.

MS. TUCKER-FOREMAN: This may not be especially appropriate right now, but I don't want to forget it and not get it said. This is Carol Tucker-Foreman with Safe Food Coalition again. The presentations from the industry continue to be couched in terms that suggest that microbiological testing of product and particularly of finished product is not and will never be scientifically valid.

I think it is fair to say that those of us on the consumer side do not accept that. To the extent that you can couch your proposals in terminology that do not tend to

foreclose or argue that this is the beginning of an era, then I think it may be easier because we don't have to work through all of that morass and argue with you about it. I would be very reluctant to be in favor of anything that got stated as foreclosing for all time the validity of ground beef testing at retail or any retail testing for other microbiological contamination.

I think we are right -- you know, the department -- we are, Dell, five years behind on all sides because the department for so many years insisted it had no authority to even regulate in that period pathogens in raw product. We have gotten past that now. The tests are being developed. I am confident that there will be tests that will come along that don't require pre-enrichment that can be a lot faster and more accurate than they are now. And I don't want to have a precedent that says we foreclose the use of those tests because they are not available now.

I thought it was ironic that last night on television, just before this meeting, there was a guy from somewhere out in Colorado saying he had a swab test for ground beef that would show it right that instant, and that some day they could sell it to people like me to use at home. Well, you know, I don't think it was a nighttime soap opera I was watching. I think it was a news report. I know it is not there.

But really, I would urge the government not to get into a situation that anybody could interpret as taking us back to an era that assumes that we can't do this. And I sure don't want anybody to discourage the development of better technology because I think we are really just opening the door to some very exciting technology in this area.

MR. ALLEN: Let me clarify -- excuse me, Dell Allen -- clarify for you. We are not asking for that. We are not discouraging it. There will be tests developed that are better, faster than what we do now. And at such time, I'm sure we will use them more. That is just the way, to me, as I have told our people, that is the boat in the future. You have just got to get ready for it.

MS. TUCKER-FOREMAN: And that is the incentive that I want us to create at the same time that we deal with immediate problems. I don't want to foreclose that incentive.

MR. ALLEN: Just a side comment. I hear from those guys probably about once a month, so --

(Laughter)

MR. BILLY: Dan.

DR. ENGELJOHN: This is Dan Engeljohn with FSIS. I have a question, I think mainly for Ann. With regard to corrective action on the carcass in the protocol that you are coming up with, what is it that you intend to do about

the carcass before and after the one that is tested? Are you looking to see if there is a potential for cross-contamination on those carcasses? And then are you intending to do any corrective action with them?

DR. HOLLINGSWORTH: If the plant -- this is Ann Hollingsworth responding to Dan's question. If the plant does not have adequate spacing so that there is a potential for cross-contamination, then yes, the two carcasses on either side would need to be addressed. We believe this has to be a plant by plant issue that needs to be looked at in the corrective action program that is put together for every individual plant as they go forward in this potential change to the directive.

MR. BILLY: All right. Two more questions, and then we'll break for lunch.

MS. SMITH-DEWAAL: Caroline Smith-Dewaal, CSPI. Can I just follow up on that? I would hope if you have got a positive that it would mean your interventions weren't working, and that we would see much more in the form of corrective action than just taking care of carcasses on either side of the positive. I mean, it is a much more significant finding. Cross-contamination might be an issue, but --

DR. HOLLINGSWORTH: I was trying to respond to Dan's specific question of the carcasses on either side.

Clearly, the rest of the corrective action program would be that you would go back and verify that your interventions steps were working or not working and why, and then make the appropriate corrective action depending on the answer to that.

MS. SMITH-DEWAAL: I mean, I would see it potentially would impact the 299 carcasses prior to the last test.

MR. BILLY: Heather.

MS. KLINKHAMER: I have a couple of questions. One is a follow-up on something that Dean said. He characterized random E. coli 0157:H7 positives as not necessarily being a process failure. And I wanted to know if that is how FSIS views an 0157:H7 positive, that it is not a HACCP process failure.

MS. STOLFA: Pat Stolfa. I'm not sure I understand the question, Heather. Could you just say it one more time?

MS. KLINKHAMER: Earlier Dean had said -- and correct me if I'm wrong -- that an 0157:H7 positive should not be considered a process failure. And I wanted to know if that was a view shared by FSIS.

MS. STOLFA: I think that Dean was speaking to the issue of the low level and the non-uniform distribution of 0157:H7 positives, or 0157:H7 on carcasses and within

carcasses that are part of the same herd, et cetera. And I think that therefore -- and, Dean, you know, you can tell me where I have gone wrong here. Therefore, it was not usefully an indicator of whether or not the process was maintained in control as we normally look at things that indicate whether or not the process remains in control. And as far as I understand the scientific data, that that is a fair way to characterize how we must take an 0157:H7 positive finding.

It is not like generic E. coli findings, which by looking at over some period of time you can get some indication of whether or not your process is in control. And I believe we generally agree with that. That doesn't say we don't think this is a serious problem that needs to be addressed somehow. But it is not a good indicator of the status of the control or non-control status of a process.

MS. KLINKHAMER: Thank you.

MR. DANIALSON: Just to follow up on that real briefly. Dean Danialson. And along the same lines, there is a coupling effect of an event on a carcass with a generic E. coli that is a good -- generic E. coli that is an indicator of gross contamination if it occurs for a process failure versus the sporadic random, and then in addition the investigative activities and the verifications of CCPs functioning and hygienic practices. It is a whole mixture

of events and activities that would couple with a positive finding if it occurred.

MR. BILLY: Rosemary, you have the final word before lunch.

MS. MUCKLOW: Could I just get Warren Mirtsching to clarify for us so that we go all away -- because a lot of us are not number people, and he keeps talking about six log reductions. In a percentage basis, Warren, what is a six log reduction?

MR. MIRTSCHING: A six log reduction represents 99.999 percent competence factor in risk minimization. Six logs equals that. So it is a fairly high competence factor that I think you could take to Las Vegas with you.

MS. MUCKLOW: Thank you.

MR. BILLY: We have nine more presenters, so I would like you back here promptly at 1:30.

(Whereupon, at 12:25 p.m., a luncheon recess was taken.)

remains intact and that a positive sample represents only the lot tested and not the entire production day. Further isolation and disposition requirements of positive lots should not change.

It should be recognized that great strides in the control of 0157 have already been made and extensive research is underway which will undoubtedly provide additional direction. The three initiatives just discussed have great merit and will provide further enhancement of the ability to control 0157. Jack-in-the-Box and Dave Theeno implore the agency to be supportive of these efforts and to table further regulatory controls until we can all gather the data from these three programs.

As the company that has the most experience in data regarding 0157 testing and control, Jack-in-the-Box believes that a much improved control system is closer today than it has ever been. This problem can and will be solved by all of us, including the regulatory and consumer advocacy communities working together to achieve one common goal, the elimination of the threat of 0157 from our food supply.

Thank you very much.

MR. BILLY: Thank you. The next person on my list is Marty Holmes.

MR. HOLMES: Marty Holmes, North American Meat Processors. I would like to change gears here a little bit

and talk about the part of the clarification policy that addressed mechanically tenderized product. To this point, we have mainly focused on trimmings and carcass testing.

The North American Meat Processors Association represents over 350 companies that process beef and other types of meat and poultry products. Many of our members and beef processors from other organizations, including the great majority of all retail stores, rely on mechanically tenderizing products to satisfy their customers. The process is used not only on high quality choice and prime grade sub-primal cuts, but it is used to a large degree on select and lower grade products to assure their palatability and tenderness.

The process acts like an insurance policy for tenderness and enhances consumer satisfaction, both at the food service and retail levels. We feel for a number of reasons that it is unreasonable to put this entire industry that uses mechanically tenderized product in jeopardy without some undeniable proof that the use of mechanically tenderized products represents a risk to human health.

Given the fact that the National Advisory Committee for the Microbiological Criteria for Foods recommended a full risk assessment of these type of products be done prior to any regulatory action being considered, and the fact that no cases of 0157:H7 food borne illness

associated with mechanically tenderized products has ever been documented by CDC or anyone else that we are aware of, and that each carcass is treated with pathogen intervention methods, and further must pass a zero tolerance check before entering commerce, and that the cuts are trimmed further before being tenderized or cut into steaks so that the external surface from the original carcass, even if it had been contaminated in any way, never actually reaches the mechanical tenderizer.

In the only data and research conducted to date, which will be presented next, that even suggests a possible contamination with inoculation levels far beyond any levels currently found to be documented in industry, exist -- excuse me. Let me rephrase that. The only data and research conducted to date suggests that the possible contamination levels on the inoculated product is far beyond what can be found in industry currently.

Consequently, we fail to understand why FSIS is not including a risk assessment of its process critical to the well-being and possibly ultimate survival of an industry in their current 0157:H7 risk assessment study. We feel that USDA must do a full risk assessment regarding non-intact mechanically tenderized products before any regulatory changes are considered since these products play such a vital role in the nation's food supply.

MR. BILLY: Thank you. And I think the next presenters, Jim Marsden and Randy Phebus, are also dealing with the same issue. So why don't we move ahead with their presentation, then we can get comment and questions.

DR. MARSDEN: Thank you, Tom. I'm here today with Dr. Randy Phebus from Kansas State University to discuss the results of a recent study that we conducted to address this issue of non-intact steaks. The copy of the slides actually is available out there, if you haven't already picked one up. The title of the study is "E. coli 0157:H7 Risk Assessment for Production and Cooking of Blade Tenderized Beef Steaks."

In this study, we intentionally inoculated beef cuts with high levels of E. coli 0157:H7 in order to quantify the effects of mechanical tenderization on the trans-location of bacteria from the surface of those beef cuts into interior muscle. E. coli 0157:H7 was used in order to obtain data specific to the pathogen of concern. The levels of contamination used in this study do not reflect levels that are likely to be present. In actual practice, the source point of contamination for E. coli 0157:H7 is at the carcass level, and contamination is prevented or reduced through the application of HACCP, including validated anti-microbial technologies and enforcement of USDA's zero tolerance policy for physical

defects.

The potential for contamination is further reduced by the removal of the carcass surface by trimming before mechanical tenderization occurs. Even by applying worse than worst case inoculation levels, our study demonstrated that there is no difference in risk between intact and non-intact steaks over the range of cooking procedures from rare to well-done. Both intact and non-intact steaks are safe for consumers. Any recommendation to address cooking temperature would apply equally to intact and non-intact steaks.

And with that, I will introduce Dr. Phebus, who will talk about the procedures for the study.

DR. PHEBUS: All right. This is literally data fresh off the grill, as you might say. And I appreciate the opportunity to present it because I think it is very important as we go forward with future risk assessments with this type of product. I think the data will be very beneficial for you. There has been a lot of people involved with this and a lot of industry support in getting the work done, so I think we have all pulled together to bring this to you.

We are currently going to present data on blade tenderization process. We have studies that are underway with the restructured type products, and we are also looking

at beef and pork issues here. In case you don't know what a blade tenderization unit looks like, that is the blade tenderization unit. And that is the tenderizing head that is associated with it. And actually, there are two heads, and I'll further describe that with some cartoons here.

First of all, the system works by taking the sub-primal underneath the heads with a moving stainless steel belt. And that belt moves one and a quarter inch forward and a half inch laterally each cycle. And the result of that is 32 penetrations per square inch. And that is pretty much the standard, I think, in the industry.

Our objectives of these studies, first of all, were to quantify and microscopically visualize the magnitude and depth of sub-surface penetration of surface inoculated 0157 due to the blade tenderization process of beef top sirloin sub-primals. Then secondly, we wanted to determine and compare the effectiveness of all of the cooking temperatures, rare to well done, on reducing populations that might be carried into the center of the steaks.

Starting with the study one, depth of penetration -- I am going to do these pretty quickly -- we uniformly misted the inoculum on the surface of these sub-primals, and we did this at a high inoculum level which was grossly high, ten to the sixth per square centimeter, and then a lower level, ten to the three per square centimeter, and allowed

them to attach for 30 minutes.

We then passed the sub-primals through the blade tenderization unit. After that, we excised three two inch diameter cores with a sterilized coring device from the bottom up so that we weren't carrying contamination in artificially with our coring method. And basically, each core represented 100 penetrations of the needle.

And this would be a representative core. And the arrows you can see represent the way that the blades penetrate, the direction. We took this core and aseptically evaluated the first centimeter, the second centimeter, and then the fourth and the sixth centimeters, and took those sections and cultured them and enumerated the organisms that were carried in. What we found -- and this, I might say, has been six replications done in triplicate. E. coli 0157:H7 from the surface was carried into the center, and it was at about a 3 to 4 percent rate, and that was uniform across high and low inoculum conditions.

And when we looked at the numbers, these were the numbers we found. I put up the lower inoculum level, which is still worse case in true life, but it is still more representative. If we have 3,000 on the surface, we would carry in about 100 to the geometric center, which would be about this point. Then the subsequent steaks that we cut off of that sub-primal would have the inoculum at the

center.

Okay. So 3 to 4 percent is what we have in the center. We then went to the cooking studies to see what level of control was needed to take care of that 3 to 4 percent. And we looked at again inoculating the surfaces with a five strain mix of E. coli at ten to the six per square centimeter. And then we again tenderized the units. We also looked at non-treated, non-tenderized controls, which are intact steaks.

All the sub-primals were uniformly hand sliced, and we looked at three different weights, which in effect was three different thicknesses, those being a half inch, three-quarter inch, and 1.25 inch. And from our surveys, that pretty much represents the industry. The steaks, which were tenderized and non-tenderized, were randomly assigned to one of five target internal cooking temperatures being 120 to 170. Actually, we considered 130 rare, 170 well done, and we put in the 120 just to complete our graphs and things. We also evaluated a non-cooked inoculated control to establish our initial levels.

We cooked these steaks in an oven, and that oven was at 300 degrees Fahrenheit, and monitored the internal temperature by inserting a thermocouple attached to our data log-in system. This thermocouple was in the geometric center of the steak to monitor. And we monitored the

temperature every ten seconds. Immediately after cooking reached the internal target temperature, we brought the steaks off the grill into a plastic bag and immediately went into an ice bath to stop the temperature rise, and we continued to monitor temperature until we cooled to 100 degrees Fahrenheit.

Then we went and analyzed these steaks to see how much was left of the E. coli populations. And I'll turn it over to Dr. Marsden at this point to discuss the data that we actually found.

DR. MARSDEN: This slide shows the log reductions in E. coli 0157:H7 across the various temperature ranges. 130 here, as Dr. Phebus said, represents a rare cooked steak. And you can see that we are looking at for the non-intact steaks a log reduction of just over five logs. The number on top is standard deviation, which was .8. For the intact steak, it was right at five logs. And this 130 temperature is pretty much, I think, the lower limit in terms of the thermal process required to control these levels of E. coli 0157:H7, assuming that you are looking at a five log reduction.

And even then, with those high standard deviations, you are pretty much right at that limit. As we move forward in temperature, 140, 150, 160, 170, we got a six log reduction across the top. And even more

importantly, you can see that the variation is much less at 140 degrees and higher. So the data at 130 I'll explain in a little bit more detail in a moment. But that is pretty much the lower limit. Next.

Okay. Now this slide shows the target versus final endpoint temperatures. And we had done some preliminary work that suggested that the temperature continues to climb quite a bit if you don't put it in ice and slow that process down. And even with putting it in ice and slowing down the temperature rise, there still is a significant temperature increase. At 120, the actual temperature crept up to 126 to 135, at 130, 137 to 142, and so on. In practice, this would actually add to the lethality of the process, of course, and even more so than we are seeing here because in practice obviously you are not going to put the steak in an ice bath. The temperature is going to continue to climb after it is cooked. So we feel that that would provide some additional lethality. Next.

Okay. Now at 130 degrees -- I put this up so that you can see the difference in the three different thicknesses. We had the 5 ounce, the 8 ounce, the 12 ounce weight steaks. In the tenderized steaks, the log reduction at 5 ounce was 5.5 plus or minus .9, the .9 being the standard deviation; 8 ounce, 5.3 plus or minus 1.1; and for 12 ounce, 6.2 log reduction plus or minus .4. So relative

to the 12 ounce or thicker product, cooking it to the rare temperature was quite sufficient to absolutely assure effective control.

For the thinner products, the 5 ounce and 8 ounce, if you factored in that standard deviation, you may not always be achieving a five log reduction. This same trend held true also for the non-tenderized steaks. So really the issue at 130 is not to do with intact versus non-intact. It is just that you are riding the lower control in that relative to controlling E. coli 0157:H7. Next.

Okay. So this -- you can go on. That basically just explains what I have just said. Okay. So in considering the 130 degree question, which again is the most rare temperature that was evaluated, it is important as the agency moves forward with a risk assessment to consider what constitutes a likely worse scenario contamination level, then determine the margin of safety desired. If we use ten to the three, for example, as the worst possible surface contamination level, which I understand has been done in other risk assessment studies, then you would actually need a one log reduction to control the microbial population. And then if you added a two log margin of safety, that would put you at a 3D thermal process.

We are obviously well above that with the 130 degree cooked. But in terms of risk assessment, those

things really need to be defined. Another thing is that the oven broiling method is what we are referring to when we talk about this lethality. This is a method that provides some consistency, and it may be useful to go back in the future and look at other cooking methods as well to see whether the same results are obtained.

Okay. If a five log reduction is what is required, then the 130 or rare temperature is not going to always provide a five log reduction because of that variation, especially in the cuts that are thinner. In the 12 ounce or thicker cuts, that really -- it was actually sufficient.

In summary, statistical evaluations of data were based on target internal temperatures. At the lowest target internal temperature of 120 and 130 degrees, the internal temperature after removal from the oven rose considerably, 10 to 11 degrees Fahrenheit. Of course, as we mentioned, this additional temperature rise actually results in a greater log reduction, a greater lethality in the thermal process, and would actually work to make the products even safer. Next.

The 120 degrees temperature, which we did basically just to establish the point where we are unable to control, we saw a 3.2 log reduction in E. coli 0157:H7 populations with a large standard deviation 1.6 logs. For

the non-tenderized steaks, we had a 5.2 log reduction, with a standard deviation of two logs. So clearly, 120 is too low of a temperature to affect control. And even though we did get the five log reduction at 130 degrees, the standard deviations were considerable, up to 1.8 logs.

To assure the greatest margin of safety based on the work that has been done to date, if steaks were cooked to an internal temperature of 140 degrees, you would have absolute assurance in all cases of control. At 130 degrees, you would have control for the thicker steaks. It is still an open question really about whether or not you could get five logs, depending on how much increased lethality was associated with the additional rise in temperature post-cooking.

Some points I wanted to make just in general. Meat safety, of course, is a function of the integrated pathogen control measures throughout processing. And we have talked about that all day. Validated anti-microbial interventions during processing greatly decrease the likelihood of even low levels of pathogens being present on sub-primals destined for blade tenderization, decreasing the level of process lethality required during cooking of tenderized cuts.

So we really don't know just exactly what level of control is necessary. I don't believe that it is five logs.

In all probability, a risk assessment would show a lower requirement. But the data I have just showed you shows you what is required to get the five logs. Importantly, I think all the data shows that there is no difference in risk between intact and non-intact steaks at cooking temperatures ranging from rare to well-done, and also that both intact and non-intact steaks are safe for consumers. And I think this goes a long way to explaining why we haven't seen epidemiology associated with this whole category of products.

The detailed results of this study will be submitted to FSIS during the comment period. And also we'll be writing a scientific paper for submission to a peer reviewed journal. Thank you.

MR. BILLY: Thank you very much. I would like to open it up for comment now on the last couple of presentations, sets of comments. Any questions or comments?

MR. DUGUAY: Mr. Billy, I have got a couple of comments from -- I am Tony Duguay, Jac Pac Foods. My company is the manufacturing segment of this industry, where many, many products come in from our various supplies for grinding, for steaking, for cooking.

In everything I have heard this morning, in all of the information we have had over the past couple of months on this issue, Jac Pac is looking -- and anyone in this